REMARKS/ARGUMENTS

Status of the Claims.

Claims 23-30 are currently pending in this application with claims 1-22 being withdrawn from current consideration. Claims 23 and 29 are amended herein to more clearly claim the current embodiments, while claims 25 and 27 are amended herein for grammar/spelling issues. The changes introduce no new matter and are fully supported by the application as filed. The current Office Action rejected claims 23-25, 26, and 28 as allegedly failing to comply with the written description requirement of 35 U.S.C. §112, while claims 23-28 and 30 were rejected as allegedly anticipated under 35 U.S.C. §102(b) by Penichet *et al.* (*J. Immunol.*, 1999, 163:4421-4426) and under 35 U.S.C. §102(a) by WO 01/07084. Additionally, claim 29 was rejected under 35 U.S.C. §112, first paragraph, as allegedly containing new matter. Applicants respectfully amend in part and traverse in part.

Amendments to the claims.

In order to more clearly claim the current embodiment, claim 23 is amended herein to specify that the compositions of the invention specifically do not comprise biotin or biotinylated molecules/moieties. Support for such change is replete throughout the application as filed. For example, paragraphs 11 and 13 describe the specific absence of biotin/biotinylated molecules from the cytotoxic moieties and Examples 1, 2, etc., detail such cytotoxic moieties and their use in compositions that do not comprise biotin/biotinylated molecules. Claim 29 is also amended herein to more clearly claim the current embodiments. Support for such change can be found, *e.g.*, in paragraph 36.

Additionally, claim 25 is amended herein to correct grammar and claim 27 is amended to correct a spelling error.

Because the changes introduce no new matter, Applicants respectfully request their entry.

35 U.S.C. § 112.

Claims 23-25, 26, and 28 were rejected in the current Office Action as allegedly failing to comply with the written description requirement of 35 U.S.C. §112, first paragraph. Applicants respectfully traverse.

The Office Action alleges that the specification does not adequately describe "targeting moiety" and that while the specification does contain numerous receptors and ligands, that Applicants do not "appear to have reduced to practice any other targeting moieties and receptors except anti-transferring [sic] receptor antibody-avidin conjugate." The Office Action apparently reasons that given the possible range of targeting moieties and given that, allegedly, Applicants do not show reduction to practice of any other targeting moiety, the "disclosure of [such] single species is insufficient to describe a highly variant genus and the artisan would not be able to recognize that applicant was in possession of the invention."

As put forth in the M.P.E.P. §2163 *et seq.*, determination of adequate written description to show possession under 35 U.S.C. §112, first paragraph, can be shown in many ways. For example, while possession may be shown by describing an actual reduction to practice, an "adequate written description of the invention may [also] be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention." M.P.E.P. §2163(II)(A)(3). "Just because reduction to practice is sufficient evidence of completion, it does not follow that proof of reduction to practice is necessary." *Id.*

Even when claims are drawn to a genus (*e.g.*, targeting moieties that bind to a cell) actual reduction to practice is not necessarily required because written description of a requisite number of species can be satisfied by "disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus." M.P.E.P. §2163(II)(A)(3)(ii). The M.P.E.P. describes a representative number of species as a variable term. Thus, an applicant must describe "a sufficient variety of species to reflect the variation within the genus." *Id.*

Thus, Applicants respectfully submit that actual reduction to practice of all targeting moieties is not required. Applicants show adequate written description and more than adequately describe the genus of targeting moieties by, *e.g.*, giving a large number of examples (both of specific targeting moieties and types of targeting moieties as well as of a wide range of specific cell surface proteins/carbohydrates and types of cell surface proteins/carbohydrates that can be targeted by the targeting moieties). For example, paragraphs 33-34 list numerous targeting moieties and targeting moiety types (*e.g.*, antibodies, antibodies against cell surface receptors, antibodies against specific cell surface receptors, etc.). Numerous examples are also presented of cell surface proteins/carbohydrates that can be targeted by the targeting moieties (*e.g.*, receptors, growth factor receptors, specific growth factor receptors, etc.). The targeting moieties, no matter the type or specific example, share the common property of binding a protein/carbohydrate of the cell surface.

Determination and knowledge of moiety biding to cells is basic to the art; thus those of skill would easily be aware of Applicants' parameters and would see that possession of the claimed invention existed. Because those of skill in the art will be very familiar with detecting binding of such targeting moieties as described herein with a cell (such as an antibody binding a cell surface receptor, *e.g.*, a transferrin receptor) and would understand that Applicants had possession, adequate written description is present. Because adequate written description is present, Applicants respectfully request that the rejection be withdrawn.

35 U.S.C. § 102(b).

Claims 23-28 and 30 were rejected in the current Office Action as allegedly anticipated by Penichet *et al.*, *J. Immunol.*, 1999, 163:4421-4426. Applicants herein amend claim 23 (from which the other pending claims depend) and traverse to the extent that the rejections are applied to the amended claims.

The Office Action emphasizes that the current claims are drawn to compositions rather than methods and alleges that Penichet "teaches an antibody-avidin fusion protein specific for the transferring [sic] receptor." The Office Action also alleges that Penichet teaches "a pharmaceutical carrier for study of pharmacokinetics and brain delivery of the antibody-avidin fusion proteins."

In order for a reference to anticipate a claim "the reference must teach every element of the claim." M.P.E.P. §2131. Additionally, "the identical invention must be shown as in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Furthermore, while not an *ipsissimis verbis* test, "every element of the claimed invention must be identically shown in a single reference," and the "elements must be arranged as in the claim under review." *See, In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Applicants respectfully submit that Penichet does not present all the required elements, let alone the elements as arranged in the current claims. For example, while Penichet teaches antibody-avidin constructs, the current claims are drawn to specific types of compositions not just the constructs (*i.e.*, compositions that comprise a targeting moiety-avidin construct along with a pharmaceutical carrier but which do not comprise biotin or biotinylated molecules).

The Office Action states that Penichet teaches carriers. However, whether Penichet teaches carriers does not anticipate the current compositions since Penichet does not teach compositions having targeting moiety-avidin constructs along with a pharmaceutical carrier but not comprising biotin or biotinylated molecules.

Because Penichet does not recite all of the limitations of the claims as amended, Applicants respectfully request that the rejection be withdrawn.

35 U.S.C. § 102(a).

Claims 23-28 and 30 were rejected in the current Office Action as allegedly anticipated by WO 01/07084. Applicants herein amend claim 23 (from which the other pending claims depend) and traverse to the extent that the rejections are applied to the amended claims.

Here too, the Office Action emphasizes that the current claims are drawn to compositions rather than methods and alleges that WO 01/07084 "teaches the claimed product" in its claims 6-7 along with avidin and similar molecules in its claim 1. The Office Action also alleges that WO 01/07084 teaches a "pharmaceutical carrier for study of pharmacokinetics and brain delivery of an antibody-avidin fusion protein."

As stated above, in order for a reference to anticipate a claim "the reference must teach every element of the claim." M.P.E.P. §2131. Additionally, "the identical invention must be shown as in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Furthermore, while not an *ipsissimis verbis* test, "every element of the claimed invention must be identically shown in a single reference," and the "elements must be arranged as in the claim under review." *See, In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Applicants respectfully submit that WO 01/07084 does not present all the required elements, let alone the elements as arranged in the current claims. For example, while, similar to Penichet above, WO 01/07084 teaches antibody-avidin constructs, the current claims are drawn to specific types of compositions not just the constructs (*i.e.*, compositions that comprise targeting moiety-avidin constructs along with a pharmaceutical carrier but which do not comprise biotin or biotinylated molecules).

The Office Action states that WO 01/07084 teaches carriers. However, again as with Penichet above, whether the reference teaches carriers does not anticipate the current compositions since WO 01/07084 does not teach compositions having targeting moiety-avidin constructs along with a pharmaceutical carrier but not comprising biotin or biotinylated molecules.

Because WO 01/07084 does not recite all of the limitations of the claims as amended, Applicants respectfully request that the rejection be withdrawn.

35 U.S.C. § 112, New Matter.

Claim 29, which was added in the previous response, was rejected in the current Office Action as allegedly presenting new matter. Applicants herein amend and traverse to the extent that the rejection is applied to the amended claim.

The Office Action alleges that "newly presented claim 29 contains the limitation that the targeting moiety is a chemical conjugate" and that 'the support pointed to by applicant . . . on paragraph 35 and 36 is not found." Applicants herein amend claim 29 to more clearly claim the current embodiment. The currently amended claim emphasizes that the targeting moiety and the avidin moiety can be chemically conjugated to one another. Paragraph 36 of the specification states that "the targeting moiety (i.e., antibody, receptor ligand or scFB)

may be conjugated to the avidin moiety using conventional chemical conjugation techniques." Thus, the currently amended claim is supported by the text of the application as filed.

Because the language of the amended claim is supported by the language of the application, it does not present new matter. Therefore, Applicants respectfully request that the rejection be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this Response, please telephone the undersigned at (510) 769-3507.

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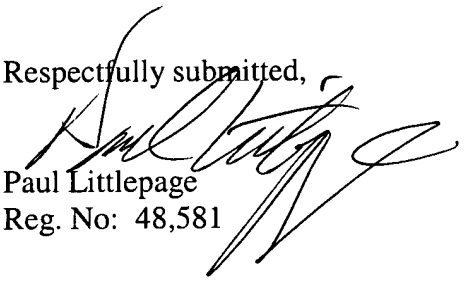
Respectfully submitted,



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